



Endovascular Repair of Thoracoabdominal Aortic Aneurysms[☆]

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KEYWORDS

Thoracoabdominal aneurysm;
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Branched graft;
Fenestrated graft

Abstract *Objectives:* To evaluate the early outcomes following thoracoabdominal aortic aneurysm (TAAA) repair utilising fenestrated and branched endografts.

Design and materials and methods: A prospective analysis of all patients undergoing endovascular repair of TAAA in a single academic centre. All patients were deemed unfit for open surgical repair. Customised endografts were designed using CT data reconstructed on 3D workstations. Post-operatively all patients were evaluated radiologically at hospital discharge, at 6, 12, 18 and 24 months, and annually thereafter.

Results: Thirty-three consecutive patients (30 males) were treated over 33 months (August 2006 to April 2009). Median age and aneurysm size were 70 years (range 50–83 years) and 64 mm (range 55–100 mm) respectively. 114/116 (98%) of the targeted visceral vessels were successfully catheterised and perfused. The in-hospital mortality rate was 9% (3/33). Transient spinal cord ischaemia was diagnosed in 4/33 (12%) patients, and permanent paraplegia in one (3%). The median follow-up period was 11 months (range 1–33 months). Endoleaks were identified in 5/33 (15%) patients: type II in four patients and a type III endoleak in one patient which required the only secondary intervention. During follow-up, two patients died: one from stroke and the other from myocardial infarction 9 and 29 months respectively after the procedure.

Conclusion: This preliminary study, which includes our learning curve, confirms the feasibility and safety of the endovascular repair of TAAA in high-risk patients. Meticulous follow-up to assess sac behaviour and visceral perfusion is critical in order to ensure optimal results of these complex endovascular repairs requiring numerous mating components.

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Table 1 Patient characteristics and aneurysm morphology.

Patient demographics	Median age (years)	70 (range 50–83)
	Male gender	30/33
Comorbidities	ASA grade III or higher (%)	25/33 (76)
	Hypertension (%)	19/33 (58)
	Coronary artery disease (%)	15/33 (45)
	Left ventricular ejection fraction <35% (%)	8/33 (24)
	Diabetes mellitus (%)	2/33 (6)
	COPD (%)	14/33 (42)
	Home oxygen (%)	3/33 (9)
	Baseline creatinine > 1.5 mg/dl (%)	7/33 (21)
	Prior aortic surgery (%)	10/33 (30.3)
	Crawford type I (%)	1 (3)
Aneurysm characteristics	Crawford type II (%)	7 (21)
	Crawford type III (%)	12 (37)
	Crawford type IV (%)	13 (39)
	Median maximal diameter (mm)	64 (range 55–100)

Introduction

The 5-year survival and repair-free survival rates for large (>6 cm) thoracoabdominal aneurysms (TAAA) managed non-operatively are 39% and 17% respectively.¹ The annual rupture rate in this setting is estimated at 14%,² indicating that this condition represents a considerable risk to life. The first operative repair of a TAAA was described by Etheridge in 1955³ and since then, despite advances to limit morbidity and mortality, complication rates remain high. Mortality rates vary between 3% and 21% in the published literature and when national and regional registry figures are analysed, the figure is invariably toward the upper end of this spectrum.^{4–6} Spinal cord ischaemia (SCI) occurs in between 4% and 11% of patients.^{4–6} The risk of paraplegia in patients with type II TAAA can rise to 25% in low-volume hospitals and in places where no adjunctive methods such as distal aortic perfusion or neurological monitoring are performed. Cardiopulmonary and renal morbidity are also high with renal failure requiring dialysis occurring in up to 15% of cases.⁷ Because of these high morbidity and mortality rates alternative approaches have been sought, with two approaches currently under evaluation. In the first, the “hybrid approach”, visceral perfusion is safeguarded by means of an extra-anatomic bypass followed by endovascular exclusion of the entire aneurysm. This approach has the advantage of limiting the exposure required to a laparotomy while avoiding a thoracotomy, although in unfit patients this remains a considerable undertaking. Early results^{8–10} in terms of mortality, SCI and morbidity rates generated great enthusiasm. Unfortunately, more recently reported data^{11,12} are less favourable with morbidity and mortality rates comparable to those of the standard open surgical technique. Currently, the hybrid technique is restricted to patients with no other reasonable options, such as emergency cases or high-risk patients with anatomy unfavourable for a branched endograft.

The second technique in evolution is a totally endovascular approach utilising specifically constructed branched modular aortic grafts. The rationale for this approach grew out of good initial experience with fenestrated grafts developed to treat juxta-renal aneurysms by endovascular

means.¹³ Preservation of visceral flow is achieved by means of either fenestrations or branches or a combination of both on the component deployed in the region of the visceral arteries. Standard aortic grafts are deployed proximally and distally to achieve exclusion of the aneurysm sac. Design of these individualised grafts is technically demanding, requiring three-dimensional reconstruction of thin-slice CT images on a workstation to allow accurate orientation of the fenestrations or branches toward their target vessel in all planes. Initial reports of the technique have all been from single-centre studies and are non-randomised and confined to patients deemed unfit for open repair. Published 30-day mortality rates range from 5.5% to 9.1% in the larger series with rates of 0–25% in the smaller series.^{14–23} Rates of SCI and cardiopulmonary and renal morbidities appear to be largely in concordance with rates observed following open repair, despite the endovascular patients being an inherently less robust population medically. In summary, despite the complexity of this technique, experience worldwide is increasing abreast with overall experience with endovascular techniques in general, and outcomes in unfit patients appear similar to those achieved with open surgery in fit patients.²⁴ With these factors in mind we wish to present our medium-term results with the first 33 cases performed at our institution in order to add these data to the growing body of evidence in favour of this technique.

Materials and methods

From August 2006 to July 2009, 33 consecutive patients with thoracoabdominal aortic aneurysm treated with custom-designed branched endovascular devices were evaluated in a prospective fashion. Written informed consent was obtained from all patients. Preoperative assessment included cardiac stress tests and selective coronary angiography based on the results, trans-thoracic echocardiography, pulmonary function testing, routine blood work, and physical examination. All patients enrolled were considered unfit for open surgery. Patient characteristics are outlined in Table 1. No patients presenting with connective tissue disease were included.

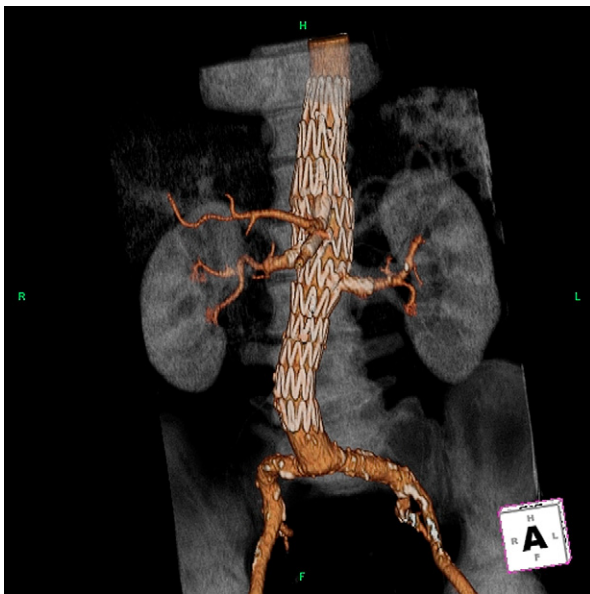


Figure 1 3D-VR reconstruction of the post-procedure CT scan of a device with four reinforced fenestrations. This design was used to treat a type III thoracoabdominal aneurysm developed after previous type IV TAAA open tubular repair. The aortic lumen was narrow at the level of the visceral arteries allowing the use of four reinforced fenestrations mated with Advanta stent grafts (Atrium Medical Corporation, Hudson, NH, USA).

High-resolution computed tomography (CT) scans were used to evaluate the entire aorta and images were assessed on a 3D imaging work station (Aquarius WS, Terarecon Inc, Mateo, CA, USA).

Device construct

Fenestrated endografts have been developed to compensate for poor proximal (infra-renal) sealing zones in the case of juxta-renal abdominal aortic aneurysms. Current early reports describing this technique and its clinical outcome are very favourable.^{25–32} At present, these devices are only manufactured by Cook Medical® (Bloomington, USA) and the Zenith endograft forms the basis of this device. A “CE mark” has been issued, and the devices are currently undergoing FDA clinical trials in the USA to confirm their safety and efficacy. More recently endografts with side branches sewn to the graft fabric have been developed and a wide range of endografts combining fenestrations and branches can now be manufactured to very precisely match the anatomy of complex TAAAs. Fenestrations consist of a circular opening in the graft fabric circumferentially reinforced with a nitinol ring which is mated with a balloon-expandable stent graft deployed into the target vessel. Directional side branches consist of a 6- or 8-mm polyester graft sewn to the aortic prosthesis above the target vessel which is mated with a self-expandable stent graft deployed in the target vessel.

A detailed description of TAAA endograft design and implantation technique has been described elsewhere.³³ It can be briefly summarised as follows:

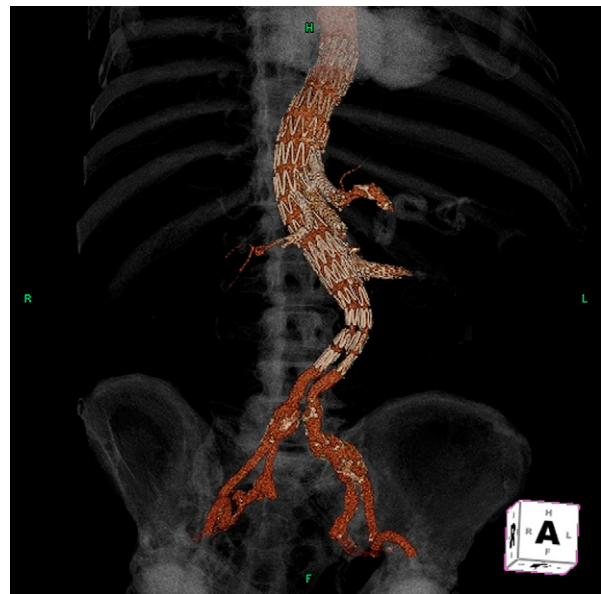


Figure 2 Six-month follow-up CT scan of a four-branched device used to treat a type III TAAA which developed 12 years after aorto-bi-iliac open repair of an infra-renal AAA. In this case the large aortic lumen (10 cm) allowed the use of four caudally oriented branches mated with Fluency grafts (CR Bard, Murray Hill, NJ, USA) to perfuse the visceral vessels.

Device design

Device lengths and visceral vessel positions were calculated from the centrelines of flow reconstructions. The general concept can be summarized as follows:

- The proximal and distal sealing zones of the device are positioned over healthy arterial segments (>20 mm).
- If the gap between the deployed endograft and the aortic wall bearing the target vessel is less than 10 mm, fenestrations are employed (Fig. 1). If this gap is >10 mm, then the target vessels are perfused using branches (Fig. 2). In the same endograft it is possible to combine fenestrations and branches (Fig. 3).
- The anatomy of the target vessel also has an impact on the endograft design. When the angulation between the aorta and the target vessel is <60°, selective catheterisation of this vessel through a fenestration, via femoral access, can be challenging. In this setting, the diameter of the aortic endograft can be reduced to accommodate a branch and facilitate access to the target vessel via a brachial approach.
- Large overlapping segments between the various endograft components and between the bridging stent grafts and fenestrations or branches are required if type III endoleaks are to be avoided.

Implantation technique

Open or percutaneous access is required to both common femoral arteries. On one side, the main body of the graft is introduced. When the endograft has been designed with

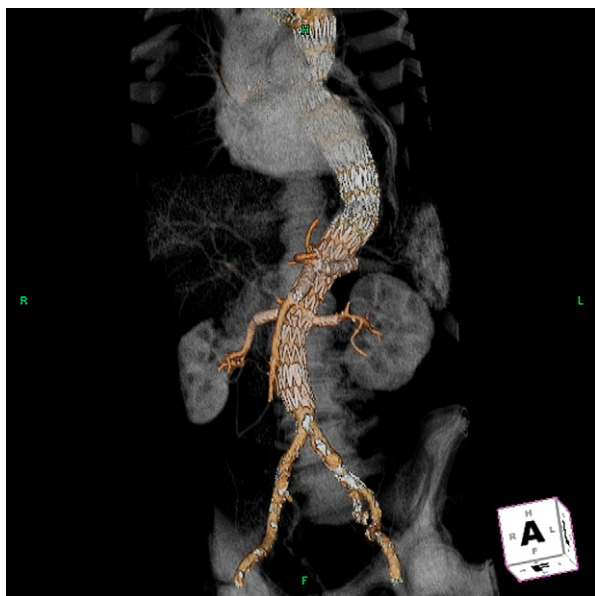


Figure 3 Anterior view of a 3D reconstruction of a type I thoracoabdominal aneurysm treated with an endovascular graft with two branches and two reinforced fenestrations. The celiac and superior mesenteric branches are perfused by helical oriented branches. They are mated with the visceral vessels with a Fluency graft (CR Bard, Murray Hill, NJ, USA). The renal arteries were incorporated into the repair with reinforced fenestrations mated with Advanta stent grafts (Atrium Medical Corporation, Hudson, NH, USA).

fenestrations, a 20 or 22 Fr sheath is inserted on the contralateral side, over a stiff wire. Under fluoroscopy the fenestrations, branches and the associated markers are recognised and the orientation of the main body of the device is checked. The fenestrated/branched body is inserted over this stiff wire to the required position so that the appropriate fenestrations are correctly aligned with their matching target vessels (checked by repeated angiographies with small volumes of contrast). The outer sheath of the delivery system is withdrawn. Through the contralateral large sheath, access to the lumen of the endograft is obtained. A side branch access sheath is then advanced on this wire and catheterisation of a target vessel through its appropriate fenestration performed. The access sheath is then advanced into the vessel over a stiff wire. The manoeuvre is repeated for each target vessel and its fenestration. Once the stent grafts are all positioned in their target vessels through the fenestrations, the diameter reducing ties of the endograft are released. The bridging stent grafts are positioned with 3–4 mm protruding in the aorta and expanded once the access sheath has been withdrawn. The aortic extremity of the bridging stent is flared with a 12-mm-diameter, 2-cm-long balloon.

When the endograft's design includes one or more branches, a hydrophilic wire is then advanced in the branch-preloaded catheter until it is in the descending thoracic aorta. A snare is advanced through a brachial sheath to capture the wire from the preloaded catheter, to create through-and-through access from the groin to the brachial artery. Over this wire, from the brachial access,

a 10 Fr sheath is advanced into the endograft and ultimately into the side branch. The target vessel is then selectively catheterised. When a stiff wire has been positioned in the target vessel, the through-and-through wire is retrieved. This latter manoeuvre is necessary to advance the brachial sheath and subsequently the bridging stent graft into the target vessel. The bridging stent graft overlaps completely the branch of the endograft and is positioned at least 2 cm into the target vessel.

The fenestrated/branched component is then connected to other proximal or distal aortic components as planned, being careful not to dislodge or disrupt the existing device, or the fenestration stents.

Perioperative patient management

Hydration and *N*-acetyl cysteine were administered before and after the procedures. During the procedure we routinely used red cell and plasma transfusions to reduce the risk of disseminated intravascular coagulopathy. Patients were routinely followed in an intensive care unit for a minimum of 12 h and spinal drainage was selectively employed depending on extent of aortic coverage or in the setting of prior aortic repair. In patients without neurological symptoms CSF pressure was maintained at 10 mmHg during the first 48 h, draining a maximum of 30 ml/h of CSF. In patients with neurological symptoms, we reduced CSF pressure to <5 mmHg. We maintained a mean arterial pressure >90 mmHg to augment spinal cord perfusion during the first 72 h post-operatively.

Follow-up

Patients underwent 64-slice CTA before discharge. Follow-up clinical assessment, laboratory testing (including eGFR evaluation), CTA, duplex ultrasonography, and plain chest and abdominal radiographs were performed at 1, 6, 12, 18 and 24 months, and yearly thereafter.

Results

Device

A total of 81 fenestrations and 35 branches were designed to perfuse the target vessels. An additional nine scallop fenestrations were positioned on the top of the branched/fenestrated endograft to allow access to the endograft lumen from a brachial approach (with an indwelling catheter). The target vessels were perfused with branches only in seven patients, with fenestrations only in 14 patients, and with a combination of branches and fenestrations in 12 patients.

Procedure

There were no conversions to open repair. We were unable to catheterise a right renal artery in two patients: this was corrected using a bypass in one patient (performed during the same procedure after the endovascular phase was completed), but in the other we elected to proceed without

Table 2 Post-operative complications.

Complication	N (%)
Death	3 (9)
Paraparesis (transient)	4 (12)
Paraplegia	1 (3)
Transient dialysis	3 (9)
Pneumonia	2 (6)
Atrial fibrillation	1 (3)

perfusing this vessel (this patient subsequently died on post-operative day (POD) 11 from respiratory failure). Completion angiography confirmed patency in 114 of the 116 (98%) target vessels (including the ilio-renal bypass). In addition to the abandoned right renal artery, there was one instance of celiac trunk occlusion. No further target vessel occlusion was depicted on the discharge CT.

Both cases of failed right renal access (including the first patient of our series) occurred in a similar setting, i.e. with the inability to correctly orientate the endograft due to a severely angulated visceral aorta.

Median operative time, media volume, and fluoroscopy dose were 232 min (range 120–390), 190 ml (range 76–300), and 9.8 mBcq/m² (range 7.2–15.3) respectively.

Mortality

In-hospital mortality rate was 9% (3/33).

- After a prolonged procedure (320 min), the patient with failed catheterisation of the right renal artery developed bronchial bleeding associated with significant thrombocytopenia. He died from respiratory failure on POD 11. This obese patient had a past history of left lung lobectomy and COPD.
- One patient died 3 days after an uncomplicated procedure. She developed cardiac failure with subsequent renal failure requiring haemodialysis. Troponin T remained in normal range (<0.25 ng/ml). Haemoglobin level was stable and there was no evidence of haemorrhage. A trans-thoracic echocardiogram (TTE) revealed a global wall motion abnormality with a mean ejection fraction (EF) of 30%. Prior to surgery, stress echocardiography had been performed. This exam revealed no wall motion abnormalities, no thoracic pain, and no ECG changes. The diagnosis of stress cardiomyopathy, or catecholamine induced cardiomyopathy, was hypothesised. This condition occurs in the absence of any other etiology, and in the setting of recent surgery that induces intense activation of the sympathetic nervous system.
- One patient died on POD 31. Sustained hypotension following the retrieval of the branched-endograft delivery system was noted intra-operatively. A right common iliac artery rupture was confirmed by an angiogram and a compliant balloon was subsequently inflated in the distal aorta before a retroperitoneal approach was undertaken. An ilio-femoral bypass was required to repair the right common iliac artery rupture. She developed multi-organ failure with liver and renal failure that required haemodialysis.

Morbidity

The median intensive care unit and hospital stays were 3.6 days (range 0–30 days) and 8.6 days (range 6–14 days) respectively.

All post-operative complications are summarised in Table 2.

Neurological complications

Only one patient (3%) developed permanent paraplegia. He was the third patient treated in our institution. The procedure was the second longest (360 min) in our experience. Although there was no prolonged hypotension, large sheaths in both iliac arteries occluded arterial flow to both internal iliacs and to the lower limbs for a prolonged time. He had a type II TAAA but no prophylactic spinal drainage had been performed. Since then, spinal drainage has been routine for type I, II, and III TAAAs.

Four patients (12%) experienced transient lower extremity weakness and numbness (two bilateral, two unilateral neurological deficit), from which they recovered during hospitalisation or in the early follow-up period. One of these was a case of delayed transient paraparesis which occurred 30 days after the procedure. This patient had been discharged on POD 7 after an uneventful post-operative course. When he was readmitted, he was dehydrated. His systolic arterial pressure was <100 mmHG. The paraparesis was reversed by administration of intravenous fluids. His antihypertensive treatment was subsequently modified.

All patients suffering neurological sequelae had extensive aortic aneurysms (three type II and two type III).

Renal complications

Three patients required haemodialysis after the procedure:

- Both aforementioned patients that developed fatal multi-organ failure;
- A patient with preoperative renal insufficiency. He was discharged with an eGFR back to its preoperative level and did not require any further dialysis after a 12-month follow-up period.

Sustained elevation of serum creatinine greater than 30% over baseline level was noted in one patient (3%) at 1-month follow-up.

Endoleaks and secondary intervention

Endoleaks were identified in 5/33 (15%) patients: type II in four patients and a type III endoleak in one patient. Only one secondary procedure was performed for a type III endoleak in the first patient of the series in whom we had performed a right ilio-renal bypass. The 6-months CT scan diagnosed sac enlargement and a persistent type III endoleak from the right renal fenestration (which we had failed to catheterise) and also from the joint between the superior mesenteric artery fenestration and its bridging stent graft. We covered the renal fenestration with an aortic cuff and added an SMA bridging stent graft. The CT scan after the secondary procedure confirmed the absence of endoleak but his last CT scan performed 29 months after the initial procedure showed a probable type II endoleak.

All four type II endoleaks remained patent during the follow-up period but none was associated with sac enlargement.

No aneurysm ruptures were reported and only the solitary aforementioned case of sac enlargement requiring a secondary procedure was diagnosed during the follow-up period.

Follow-up

Mortality

The median follow-up period was 11 months (range 1–33 months). No patients were lost to follow-up. During follow-up, two patients died: one from stroke and the other from myocardial infarction 9 and 29 months respectively after the procedure.

Device integrity and branch patency

During the follow-up period, no component separations, barb or stent fractures, or device migrations were detected.

All renal and visceral branch vessels (109/109) patent at hospital discharge remained patent on the consecutive follow-up exams.

Discussion

Despite advances in surgical technique and perioperative care, the morbidity and mortality associated with open repair of TAAA remains high. This makes the decision to intervene in patients diagnosed with TAAA a complex one which requires cognisance of multiple factors including the natural history of TAAA, the patient's general condition, the available surgical expertise and the patient's wishes. Many patients, particularly older patients are deemed unfit for open surgical repair of TAAA and it is this cohort of patients that has been studied so far in the growing experience of endovascular repair of these lesions. Intuitively, one would expect a particularly poor outcome for such patients undergoing such a procedure, but interestingly this does not appear to be the case.

The rapid evolution of imaging technology, and indeed materials technology, has permitted extremely precise visualisation of the anatomy of such aneurysms and the design of highly specific grafts tailored to suit almost every anatomical variation encountered with regard to the visceral arteries. Experience published to date varies from centre to centre with regard to the nature of devices used, with Chuter's²¹ series for example using branch grafts exclusively. Conversely, Bicknell has routinely used fenestrated grafts only when repairing TAAA.²³ In our current series we have been flexible in our approach using a combination of both types of branch to the visceral arteries. So far it is fair to say that the published data is not of sufficient volume to support the use of any one of these three approaches over another.

What would appear to be very clear from all authors is that the design and construction of the device is of critical importance, and indeed is probably the single biggest factor in successfully attaining perfusion of the target vessels. To this end fine-slice CT and 3D reconstruction facilities are mandatory.

Mortality rates in fit patients undergoing open TAAA repair approach 20% when one looks at national or regional registry figures, although in some of the larger series from high-volume centres this can be improved to between 5% and 12%.^{34–36}

Published mortality figures for endovascular repair of TAAA generally range between 5.5% and 9.1% in the larger series, although one series of four patients had a mortality of 25% and other series of between one and nine patients reported 0% mortality.^{17–19,22,23} In our series of 33 patients the 30-day mortality was 9%, a figure which is concordant with the other larger series published to date.

Spinal cord ischaemia and consequent paraplegia/paraparesis is the most feared morbidity of both open and endovascular approaches. This complication is reported to occur in 4–11% of cases undergoing open repair of TAAA.^{4–6} The largest series of endovascular repair of TAAA by Roselli reported a 2.7% paraplegia rate (2/73 patients) with both patients dying subsequently.¹⁶ A larger series from the same centre which included both TAAA and thoracic aortic aneurysms included 352 patients treated by endovascular techniques and showed a SCI rate of 4.3%, the risk for these patients being particularly associated with prior aortic surgery.²⁴ Chuter²¹ reported zero incidence of SCI in his series of 22 patients, while Verhoeven³⁶ reports SCI in 5/30 patients for an incidence of 16.7% with four recovering fully. In our own series 5/33 patients showed evidence of SCI for an incidence of 15.2%. Four of these patients had paraparesis only and made a full recovery with spinal fluid drainage or blood pressure augmentation, while one patient developed paraplegia without recovery. All of these cases occurred in patients with extensive aneurysms (mostly type II TAAA).

Renal complications were uncommon in our series with only one patient (3%) demonstrating a persistent elevation serum creatinine of more than 30% over baseline at 1-month follow-up. Three patients (9.1%) required transient dialysis perioperatively. These figures compare very favourably with those quoted for open TAAA repair where up to 15% may require dialysis.⁷

In the current series only one secondary intervention was required for a persistent type III endoleak associated with sac enlargement in a patient whose right renal artery could not be cannulated at the time of initial endovascular repair and in whom an ilio-renal bypass was accordingly performed. This was successfully treated by deploying an aortic cuff across the fenestration when sac enlargement was detected. There was no other case of sac enlargement and four type II endoleaks remain under surveillance.

It is worth bearing in mind that our series (and presumably other published series to date) included our "learning curve" and that it is likely that, as further experience is gained, outcomes will improve further. Also this series, in common with the other published series, included only patients deemed unfit for open surgical repair and compared outcomes with the open procedure in patients who were inherently healthier. Despite this significant disparity between the compared groups, outcomes appear at least similar.

Our current practice for patients with TAAA is to evaluate both the patient's physiological status and the morphology of the aorta and its branches. For example a 55-year old man with a dissecting aneurysm will be

recommended open surgery. We consider that it is unethical at this stage to treat a fit patient by an endovascular approach even if the anatomy is favourable for such a treatment, although our position will probably change when long-term data become available. On the other hand, an old patient (>75 years old) with diffuse atherosclerotic disease will be recommended to undergo endovascular repair if his anatomy is favourable for such a procedure, which is usually the case nowadays. If no complete endovascular option is possible, we will search for a limited hybrid option, combining, for example, a hepato-right renal bypass to a fenestrated/branched endograft implantation if the contra-indication for a complete endovascular treatment was challenging right renal artery anatomy. We tend to avoid the classic "hybrid option" (combining a complete extra-anatomic visceral debranching and aortic endografting) as in our hands this has not provided better results than a classic open repair in high-risk patients. We have only performed such a classic hybrid approach during the study period in two patients presenting with ruptured TAAA and strict contra-indication to left thoracotomy.

Conclusion

The current study adds further to the growing body of evidence in favour of an endovascular approach to the repair of TAAA. This study, which was carried out in an inherently high-risk patient group, suggests that the technique is safe when compared to published data for open approaches in healthier patients. The endovascular approach appears to be durable in the short to medium term with acceptable secondary re-intervention rates.

Conflict of Interest

Stéphan Haulon is a consultant for Cook Medical.

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